REMARKS

Independent Claim 1 has been amended to clarify the invention and better distinguish the invention from the prior art. No new matter has been entered.

The Examiner cites Abrams et al. for teaching the puncturing of a film to allow release. Although the Examiner does not state which Abrams patent he relies on, it appears that the relevant text comes from US Patent No. 6,026,809. Claim 1 has been amended to clarify the distinction between the puncture holes formed in the '809 patent and the puncture holes required by the current application. In the '809 patent, a single capsule is placed in the inhaler housing, and a hole is punctured in the capsule which allows the drug to spill onto a surface where it can be agitated by a piezoelectric vibrator to break apart agglomerated particles. The '809 patent contains no teaching or suggestion that the size of the puncture holes is important. In fact, the '809 patent is completely silent on the size of the puncture holes. The '809 patent relies solely on the efficiency of the piezoelectric agitation of the drug to break apart agglomerated particles. And, while the '809 patent teaches that vibration at a frequency of 12KHz will most optimally yield a suspension of particles 1 to 5 microns in size. (Column 3 at lines 35-46), there is no guarantee that the piezoelectric vibrator will prevent particles that are larger in size from also joining the suspension and being inhaled. In fact, both the '809 patent and US Patent No. 5,694,520 (Abrams et al., discussed below) rely exclusively on the piezoelectric vibrator to generate a suspension of particles sized 1 to 5 microns.

The current invention is an improvement over such devices. The current invention requires that the puncture holes are of controlled size of no more than 5 microns. This feature and advantage ensures that only properly sized particles will be delivered to a patient. In the

HAYES SOLOWAY P.C.
3450 E. SUNRISE DRIVE
SUITE 140
TUCSON, AZ 85718
TEL. 520.882.7623
FAX. 520.882.7643

175 CANAL STREET
MANCHESTER, NH 03101
TEL. 603.668.1400
FAX. 603.668.8567

'809 and the '520 patents, if the piezoelectric vibrator does not generate a suspension where 100% of the suspended particles are 1 to 5 microns in size, then the patient could inhale particles too large in size to effectively reach the respiratory tract. The current invention overcomes this shortcoming by filtering the particles for size. That is to say, the size of the puncture holes ensures that the suspension of particles delivered to the patient is of a size not greater than 5 microns. It therefore cannot be said that such improvement is merely a function of the puncturing as applied in the '809 patent.

Turning to the rejection of claims 1, 3, 8 and 13-15 as obvious from Abrams et al. (US Patent No. 5,694,520) in view of Casper et al. (US Patent No. 6,209,538), in the primary reference Abrams et al., the film covering the blisters or wells holding the drug is peeled back to expose the blisters or wells carrying the drug. (Column 5 lines 33-43). Thus, there is no puncturing of the film at all, let alone control of the size of the puncture holes as required by claim 1, or the advantages thereof as above discussed.

Moreover, maintaining the top of the blister substantially intact with only puncture holes provides other advantages. With Applicant's claimed invention, the contents of a blister pack, due to the restrictively small size of the puncture holes, remain effectively insulated from moisture and contamination. Moreover, as Applicant's claimed invention is not position sensitive and the puncture holes minimally damage the blister packer, it is another feature of the current invention that multiple doses from a single blister can be effectively given.

Casper et al. does not supply the missing teachings to Abrams et al. to achieve render obvious of claim 1. The Examiner relies on Casper et al. to supply the teaching of a flexible coiled tape. However, Casper et al. fails to supply the missing teaching of both the '809 and the '520 patents for filtering the contents of the blister pack through the feature of controlled

HAYES SOLOWAY P.C.
3450 E. SUNRISE DRIVE
SUITE 140
TUCSON, AZ 85718
TEL. 520.882.7623
FAX. 520.882.7643

175 CANAL STREET
MANCHESTER, NH 03101
TEL. 603.668.1400
FAX. 603.668.8567

size puncture as above discussed. Casper et al. teaches driving a single puncture through the top and bottom of a blister pack. Casper et al. does not teach a restriction on the size of the puncture hole. Casper et al. teaches using gravity or vacuum to draw out the contents of the blister pack. There is no attempt by Casper et al., no teaching or suggestion within the four corners of Casper et al. of a vibrator, or of controlling particle size by breaking up the particles by vibration, and filtering the particles through the puncture holes. Thus, no combination of Abrams et al. and Casper et al. reasonably could be said to achieve or render obvious independent claim 1, as amended.

Claim 3, 8 and 13-15 are all directly dependant on claim 1. The deficiencies of the combination of Abrams et al. and Casper et al. vis-à-vis claim 1 are discussed above. Claims 3, 8 and 13-15 are patentable over Abrams et al. and Casper et al. for the same reasons above adduced relative to claim 1 as well as for their own additional limitations.

Turning to the rejection of claim 9 as obvious from Abrams et al. '920 in view of Pera, claim 9 is dependant on claim 1. The deficiencies of the primary reference Abrams et al. vis-à-vis claim 1 are discussed above. Pera does not supply the missing teachings to Abrams et al. to achieve or render obvious claim 1 or claim 9. Pera has been cited as teaching dispensing an antioxidant vitamin by inhalation. However, as argued previously, Pera nowhere teaches or suggests any inhaler structure. Thus, the structural deficiencies of Abrams et al. discussed above clearly are not supplied by Pera. Accordingly, no combination of Abrams et al. and Pera can be said to achieve or render obvious claim 1 or claim 9 which depends thereon, and, the rejection of claim 9 as obvious from Abrams et al. in view of Pera is in error.

The rejection of claims 10 and 11 as obvious from Abrams et al. '920 in view of Hendricks likewise is in error. Claims 10 and 11 are dependent on claim 1. The deficiencies

HAYES SOLOWAY P.C.
3450 E. SUNRISE DRIVE
SUITE 140
TUCSON, AZ 85718
TEL. 520.882.7623
FAX. 520.882.7643

175 CANAL STREET
MANCHESTER, NH 03101
TEL. 603.668.1400
FAX. 603.668.8567

of the primary reference Abrams et al. vis-à-vis claim 1 are discussed above. It is not seen that Hendricks supplies the missing teachings to Abrams et al. to achieve or render obvious claim 1 or claims 10 and 11 which depend thereon. Hendricks teaches a dry powder inhaler in which the material comprises a hormone or steroid. However, the inhaler taught by Hendricks is vastly different in construction from Abrams et al. Hendricks does not teaching or suggest any means to modify the Abrams et al. inhaler, i.e., to form a flexible coiled tape blister pack having a top spaced crowned area formed of a frangible element through which puncture holes are formed and act as filters to prevent the ejection of over sized particles of the material as required by Applicant's claims. Accordingly, no combination of Abrams et al. and Hendricks can achieve or render obvious claim 1 or claims 10 and 11 which depend thereon, and, the rejection of claims 10 and 11 as obvious from Abrams et al. in view of Hendricks also is in error.

The rejection of claim 12 as obvious from Abrams et al. '663 in view of Shyjan likewise is in error. Claim 12 is dependent on claim 1. The deficiencies of the primary reference Abrams et al. vis-à-vis claim 1 are discussed above. It is not seen that Shyjan supplies the missing teachings to Abrams et al. to achieve or render obvious claim 1 or claim 12 which depends thereon. Shyjan teaches a bioactive material. However, Shyjan, like Pera, contains absolutely no teaching or disclosure of inhaler structure or any form of blister back for use with an inhaler structure. Thus, no combination of Abrams et al. and Shyjan could be said to achieve or render obvious claim 1 or claim 12 which depends thereon. Accordingly, the rejection of claim 12 as obvious from Abrams et al. in view of Shyjan also is in error.

Having dealt with all the objections raised by the Examiner, the Application is believed to be in order for allowance.

HAYES SOLOWAY P.C.
3450 E. SUNRISE DRIVE
SUITE 140
TUCSON, AZ 85718
TEL. 520.882.7623
FAX. 520.882.7643

175 CANAL STREET
MANCHESTER, NH 03101
TEL. 603.668.1400
FAX. 603.668.8567

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Respectfully submitted,

Norman P. Soloway
Attorney for Applicant
Reg. No. 24,315

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By M. Diane Duke

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HAYES SOLOWAY P.C.
3450 E. SUNRISE DRIVE
SUITE 140
TUCSON, AZ 85718
TEL. 520.882.7623
FAX. 520.882.7643

175 CANAL STREET
MANCHESTER, NH 03101
TEL. 603.668.1400
FAX. 603.668.8567